OCT 1 0 2007

510(k) Summary as required by section 807.92(c)

K070870

Submitted by : TRANSVERSE INDUSTRIES CO.

NO.305 HUA CHENG RD.HSIN-CHUANG

CITY TAIPEI,TAIWAN R.O.C.

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Contact Person : HO KO LIANG

Prepared On : April 02,2007

K24

Classification Name：Laser Instrument,Surgical Powered.

Common or Usual name：Light Therapy Device

Proprietary Name：Skin Care Light

Classification：The subject device satisfies the 21 CFR definition of a class 2 ,Laser surgical instrument for use in general and plastic surgery and in dermatology as follows：

Regulation Number	Product Code	Regulation Name	Review Panel
878.4810	GEX	Laser surgical instrument for use in general and plastic surgery and in dermatology.	General & Plastic Surgery

Substantial Equivalence：

Skin Care Light is substantially equivalence with the ClearLight Phototherapy Device,Model CL 420（K013623）made in Israel.Skin Care Light has the equivalent intended use and different technological characteristics.

Device Description：

Skin Care Light is a lamp intended to treat dermatological conditions by emitting visible light in blue and/or red.The energy intensity are 4,8,12mW/cm^2.The system includes a spectral band light source and some controlling keys to select light.It also includes

mechanical fixture for holding the light source at an adjustable distance and direction related to the skin treatment area,an electronic unit to control the duration,it will automatically shut off after 15 minutes.

Statement of Indication For Use :

Skin Care Light is intended to provide phototherapeutic light to the body.It is generally indicated to treat dermatological conditions. Skin Care Light is specifically indicated to treat moderate inflammatory acne vulgaris.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Transverse Industries Company
% Mr. Ho Ko Liang
President
No. 305 Hua Cheng Road
Hsin-Chuang City, Taipei,
China (Taiwan)

OCT 10 2007

Re: K070870
Trade/Device Name: Skin Care Light
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 18, 2007
Received: September 18, 2007

Dear Mr. Liang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

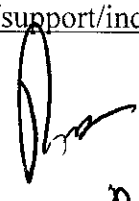
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the

quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

cc: HFZ-401 DMC
HFZ-404 510(k) Staff
HFZ-410 DGRND/GSDB
D.O.
f/t:KSB:kxl:10-04-07

OC Numbers:

Division of Enforcement A	240-276-0115
Dental, ENT and Ophthalmic Devices Branch	240-276-0115
OB/GYN, Gastro. & Urology Devices Branch	240-276-0115
General Hospital Devices Branch	240-276-0115
General Surgery Devices Branch	240-276-0115
Division of Enforcement B	240-276-0120
Cardiovascular & Neurological Devices Branch	240-276-0120
Orthopedic, Physical Medicine & Anesthesiology Devices Br	240-276-0120

Exhibit 1

Indications for Use

510(k) Number (if known) : K070870
Device Name : Skin Care Light
Indication For Use :

Skin Care Light is intended to provide phototherapeutic light to the face. It is used to treat dermatological conditions by exposing the surface of the skin to the blue spectrum. It is specifically indicated to treat moderate inflammatory acne vulgaris.

Prescription Use ___x___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH,Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070870